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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,423	09/10/2003	Tammy Burd Mehta	100/03021	4629
21569 7590 07/26/2007 CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234				
			EXAMINER BABIC, CHRISTOPHER M	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 07/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,423	Applicant(s) MEHTA, TAMMY BURD	
	Examiner Christopher M. Babic	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 16, 2007 has been entered. Claim(s) 1 and 3-10 are pending.

New Grounds of Claim Rejections - 35 USC § 112 - 2nd Paragraph

The following new grounds of claim rejections are made in view of newly discovered indefinite within the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 1 and 3-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the phrase --less than about--. The phrase --less than-- typically indicates a maximum point. The phrase -- less than-- however, is controverted by the term --about-- which implies that values above and below the recited amount of polymer. In *Amgen, inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (CAFC 1991), the CAFC stated, "The district court held claims 4 and 6 of the patent invalid because their specific activity limitation of--at least about 160,000--was indefinite". After review, the CAFC states "We therefore affirm the district court's determination on this issue." Thus, the CAFC found the phrase "at least about" indefinite where the metes and bounds of the term were not defined in the specification.

New Grounds of Claim Rejections - 35 USC § 103

The rejections of claim(s) 1 and 3-10 over Stapleton, Moreira, and Maniatis as set forth in the Office Action dated February 16, 2007 have been withdrawn in view of Applicant's amendments.

Response to Arguments

Applicant's arguments have been fully considered but they are moot in view of the new grounds of rejection presented below.

The following new grounds of rejections are made in view of Applicant's amendments.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim(s) 1, 3-5, and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. 5,856,174) in view of Chetverin et al. (U.S. 5,616,478), in further view of Moss et al. (U.S. 5,135,855).

With regard to claim(s) 1 and 8-10, Lipshutz teaches methods of performing amplification (col. 6-8, amplification, for example) and capillary electrophoresis (col. 11-12, capillary electrophoresis; col. 12, lines 30-50, sieving mediums, for example) within microfluidic devices (fig. 3; col. 14, lines 10-35, for example).

With regard to the above claims, Lipshutz does not expressly teach performing amplification reactions within an unpolymerized medium, and subsequent separation of the amplification products by flowing the product through the polymerized form of the sieving medium, within the claimed polymer concentration, i.e. comprising a polymer concentration that is less than 0.4%.

Chevretin provides a supportive disclosure that teaches the amplification of nucleic acids within sieving mediums (col. 4-6, summary, for example) such as those comprised of different acrylamide mediums (col. 12, for example). Example 3 of

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Chevretin expressly teaches the amplification of nucleic acid within a sieving medium before it is cast, i.e. polymerized into a solidified substance (col. 18-19; col. 19, lines 30-40, for example). Chevretin further teaches that sieving mediums may be impregnated with amplification enzymes before casting to prevent problems to due harsh polymerization conditions (col. 12, lines 30-40, for example). Thus, the teachings of Chevretin at the very least provide motivation for one to perform a PCR reaction before polymerization to prevent loss of enzyme activity due to harsh polymerization conditions.

With regard to claim(s) 7, Chevretin teaches thermostable DNA polymerase, (col. 19, lines 25-35, *thermus thermophilus*, for example).

Neither Lipshutz nor Chevretin expressly teach the claimed polymer concentration, i.e. comprising a polymer concentration that is less than 0.4%.

It is submitted that the optimization of polymer concentrations for use in nucleic acid separation electrophoresis procedures was well known in the art at the time of invention as demonstrated by Lipshutz (col. 12, lines 35-45, for example).

Moss provides a supportive disclosure that teaches a nucleic acid separation electrophoresis procedure comprising a polymer concentration that is less than 0.4% (col. 4, lines 25-40, 0.4% polyacrylamide, for example).

With regard to claim(s) 3-5, Moss teaches a polymer concentration that is less than 0.4% (col. 4, lines 25-40, 0.4% polyacrylamide, for example).

Thus, in summary, it is submitted that it would have been *prima facie obvious* to a practitioner of ordinary skill in the art at the time of invention to simply amplify and

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separate nucleic acids products within the well known polymer concentration as taught by Moss within the microfluidic device since Chevretin demonstrates that such amplification can take place and reduce experimentation time by combining the two procedures. Chevretin further provides motivation for one to perform a PCR reaction before polymerization of the sieving medium to prevent loss of enzyme activity due to harsh polymerization conditions.

2. Claim(s) 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. 5,856,174) in view of Chetverin et al. (U.S. 5,616,478), in further view of Mitra et al. ("In situ localized amplification and contact replication of many individual DNA molecules" Nucleic Acids Res. 1999 Dec 15;27(24):e34) as applied to claim(s) 1, 3-5, and 7-10 above, and further in view of Dubrow (U.S. 5,164,055).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach polymers comprising polyethylene oxide.

It is submitted that the use polymers comprising polyethylene oxide for nucleic acid fractionation was well known in the art at the time of invention as demonstrated by Dubrow (col. 14, lines 40-60; col. 17, lines 35-55, for example).

Dubrow provides a supportive disclosure that teaches a nucleic acid separation electrophoresis procedure utilizing polymers comprising polyethylene oxide (col. 14, lines 40-60; col. 17, lines 35-55, for example).

Conclusion

Claim(s) 1 and 3-10 are rejected. No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Mitra et al. ("In situ localized amplification and contact replication of many individual DNA molecules" Nucleic Acids Res. 1999 Dec 15;27(24):e34). Mitra teaches methods of amplification within sieving mediums (ii, col. 1, creating polony slides, for example). Mitra further teaches that polymerization may damage template molecules (iv, col. 2, discussion, for example).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 7/22/07

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